REMARKS

I. INTRODUCTION

Claims 1, 3-5 and 7-10 are currently pending in the present application. Claims 1, 3-5 and 7-10 stand rejected under 35 U.S.C. § 103(a). By the present amendment, claims 1, 3, 5, 7 and 9 have been amended. No new matter has been added by the current amendment, as support thereof can be found in the present specification at, *inter alia*, page 5, lines 6-13; originally filed claims 3 and 7; and Figure 1. Applicant respectfully submits that the pending claims are now in condition for allowance.

II. REJECTIONS UNDER 35 U.S.C. §103 (a)

Claims 1, 3-5, and 7-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,643,193 ("Papillon *et al.*") in view of U.S. Patent No. 5,744,047 ("Gsell *et al.*") and U.S. Patent No. 5,607,830 ("Biesel *et al.*"). Applicant respectfully submits that this rejection should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish

a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

Papillon *et al.* is directed to an apparatus for the collection, washing and reinfusion of shed blood. According to Papillon *et al.*, the number of components and steps needed to collect, wash and reinfuse blood is reduced in the apparatus of Papillon *et al.* "by modifying the centrifuge bowl and locating it between the surgical site and the vacuum source." Papillon *et al.*, col. 2, lines 63-64. The apparatus of Papillon *et al.* includes a tube 10 for collecting blood from a surgical site, connected via a coupling 11 to an aspiration line 12 which "connects to the inlet port 22 of a centrifuge bowl 25, which is itself part of a centrifuge apparatus 24 that comprises the bowl 25 and means for rotating the bowl which are not shown." Papillon *et al.*, col. 4, lines 7-10. According to Papillon *et al.*, a vacuum source 34 applies negative pressure thereby drawing blood from the surgical site into tube 10, coupling 11, and aspiration line 12, where the blood then "enters input port 22 and passes through the filter 42 into the separation chamber 48 of centrifuge bowl 25, which is rotating at about 2000 to 3000 rpm." Papillon *et al.*, col. 4, lines 61-63. Thus, according to the apparatus disclosed in Papillon *et al.*, the centrifuge bowl is located between the surgical site (or blood source) and the vacuum source. *See* Papillon *et al.*, abstract; figure 3.

As described in the present specification, Gsell *et al.* describes a leukocyte filter which is also used for autologous blood transfusions. Gsell *et al.* describes a filter assembly including "a housing, having an inlet and an outlet, and a filter element disposed in the housing for decreasing the leucocyte content and removing other deleterious matter from a leucocyte-containing liquid," such as blood. Gsell *et al.*, col. 4, line 57 to col. 5. line 3.

Biesel *et al.* is directed to a method for the continuous conditioning of a cell suspension. According to the method and apparatus disclosed in Biesel *et al.*, "the cell suspension is centrifuged and the separated components of the cell suspension are separately removed." Biesel *et al.*, col. 1, lines 11-13. As previously described in the Response to the Office Action mailed on March 28, 2003, the current specification has been amended to incorporate Biesel *et al.* (U.S. Patent No. 5,607,830) by reference, which is the U.S. equivalent of the previously cited German Patent No. 42 26 974.

In contrast to the teachings of Papillon *et al.* in view of Gsell *et al.* and Biesel *et al.*, the autotransfusion set of the present invention, as currently recited in independent claims 1 and 5 in amended form, includes "a blood collecting tank having an inlet and an outlet, and a device for generating a vacuum connected to the blood collecting tank, ... wherein the blood supply line includes a first section connected to the inlet of the blood collecting tank and a second section connected to the outlet of the blood collecting tank." Likewise, the method of the present invention, as currently recited in independent claim 9 in

amended form, includes the claim limitation of "wherein the blood is drawn into the blood supply line via a device for generating a vacuum which is connected to the blood collecting tank." That is, in accordance with the present invention, the device for generating a vacuum (to draw the blood into the blood supply line) is located between the patient (*i.e.*, the blood source) and the centrifuge unit (to which the separation unit is rotatably mounted).

Thus, Papillon *et al.* in view of Gsell *et al.* and Biesel *et al.* do not teach nor suggest an autotransfusion set including "a blood collecting tank having an inlet and an outlet, and a device for generating a vacuum connected to the blood collecting tank, ... wherein the blood supply line includes a first section connected to the inlet of the blood collecting tank and a second section connected to the outlet of the blood collecting tank," or a method of autologous blood transfusion "wherein the blood is drawn into the blood supply line via a device for generating a vacuum which is connected to the blood collecting tank." Therefore, Papillon *et al.* in view of Gsell *et al.* and Biesel *et al.* do not disclose nor suggest each and every element of the presently claimed invention, and Applicant respectfully submits that claims 1, 3-5 and 7-10 are thus not rendered obvious by the cited patents.

Although the Examiner has alleged that "[i]t would have been obvious to one of ordinary skill in the art to provide the Papillon *et al.* blood processing system with a high capacity filter as taught by Gsell *et al.* in order to increase the amount of blood processed" (Office Action mailed 9/10/03, page 3, paragraph 5), Applicant respectfully disagrees in regard to the pending claims in their amended form. It is respectfully submitted that a *prima*

facie case of obviousness has not been established by the cited patents because the modification of the apparatus of the primary reference of Papillon *et al.* (in view of Gsell *et al.* and Biesel *et al.*) to include "a blood collecting tank having an inlet and an outlet, and a device for generating a vacuum connected to the blood collecting tank, ... wherein the blood supply line includes a first section connected to the inlet of the blood collecting tank and a second section connected to the outlet of the blood collecting tank," would change the principle of operation of the device disclosed in the primary reference of Papillon *et al.* *See In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (court reversed rejection of claims holding that the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principles under which the [primary reference's] construction was designed to operate"). That is, Papillon *et al.* discloses an apparatus in which "[t]he location of the centrifuge bowl between the surgical site and the vacuum source used to clean the site allows the immediate collection of shed blood in the bowl without an intermediate reservoir or an additional pump." Papillon *et al.*, abstract. Thus, the apparatus of Papillon *et al.* is designed such that the centrifuge bowl is to be located between the patient (*i.e.*, the surgical site) and the vacuum source. Papillon *et al.* does not teach nor suggest a device including a vacuum source being located between the patient and a centrifuge unit, and to modify the apparatus of Papillon *et al.* to include such a vacuum source would require a substantial redesign of the apparatus while rendering the apparatus unsatisfactory for its intended purpose as it could no longer "allow[] [for] the immediate collection of shed blood in the bowl without an intermediate reservoir or an additional pump." Papillon *et al.*, abstract.

For at least the preceding reasons, Applicant respectfully submits that the rejection of pending claims 1, 3-5 and 7-10 under 35 U.S.C. § 103(a) has been overcome and should therefore be withdrawn.

III. CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,
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Dated: January 12, 2004

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